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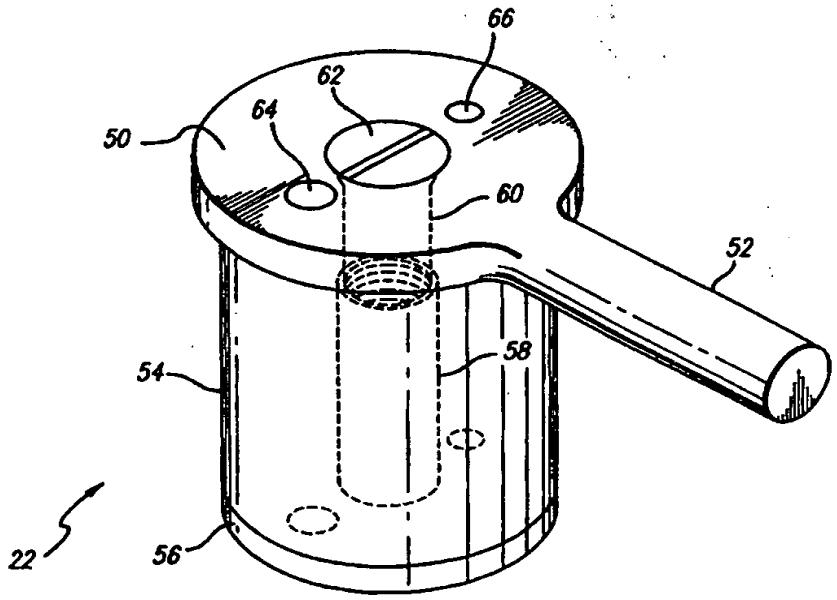

(57) Abstract

A low profile parenchymal bolt having a cap, a body, and a base with a threaded screw located through the cap that engages a threaded shaft anchored to the base. Rotating the screw into the threaded shaft causes the base to move towards the cap compressing the body and causing its outer diameter to increase into contact with an opening in the skull of a patient to form a fluid-tight seal. An off-center lumen is formed through the cap, body, and base, and moving the base toward the cap also causes the body to decrease the size of the lumen thus clamping an instrument mounted through the lumen in place in the bolt and therefore, the skull of the patient.

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EXPANDABLE PARENCHYMAL BOLT

RELATED APPLICATION

Priority for this application is claimed to provisional application no. 60/017,586 filed on May 14, 1996.

BACKGROUND

The invention relates generally to bolts used to establish a channel through biological tissue and in particular, to a parenchymal bolt used to mount an instrument, such as a catheter, into the cranium for biomedical sensing or other purposes.

It has been the practice for many years to monitor the intracranial pressure of patients suffering from severe brain injuries. If the pressure rises above a critical level, pressure in the brain should be relieved by draining fluid from the affected ventricle. Several different structures have been proposed and adopted for this purpose. A catheter or the like is one such structure and may be inserted directly into the brain to accomplish these tasks. However, insertion of a catheter has been a difficult and risky procedure and requires a high level of skill. Chief among the risks is the possibility of bacterial infection. As a general rule, once the catheter has been inserted, it must be left in place for several days, and this makes the prevention of such infection both critically important and more difficult to accomplish.

Additionally, once positioned, it is important that the catheter remain in the selected position during the entire sensing period. Should the catheter be inadvertently withdrawn from the proper position in the brain, pressure changes or temperature changes may not be sensed. If the catheter were being used to drain excess fluid, this drainage procedure may be interrupted should the catheter be partially or fully withdrawn from the skull. Movement of the patient, either on his own initiative or by others, contact with the catheter outside the patient, and other forces may put strain on the catheter shaft tending to pull it from its established position in the skull of the patient. On the other hand, the catheter must be mounted so that it can be removed from the patient when needed. For example,

removal may be required for recalibration of a sensor or for replacement of a sensor or drainage catheter.

A structure or arrangement of some type is required to stabilize the catheter so that it does not move during its period of operation in the brain. Because sensing may extend over many days, as mentioned above, the stabilizing arrangement must be robust and must provide a sterile communication with the patient to reduce the chances of infection.

In one prior approach, it is possible to insert such a catheter surgically through an opening in the skull, routing the catheter underneath the scalp against the surface of the skull for a significant distance from the opening in the skull and thence through an opening in the scalp to the outside world. This isolates the opening in the skull from contact with the environment outside the scalp and thereby reduces the opportunity for infectious agents to enter the opening in the skull. This approach has been favorably received and significantly reduces the risk of infection. However, insertion of the catheter by this method is time consuming and requires considerable surgical skill. Additionally, should the hospital staff need to remove the catheter for some reason, such as for recalibration, a substantial amount of time is required to extract it from the skull, pull it from the scalp tunnel, and reinstall it or a replacement catheter.

A parenchymal bolt structure, such as that shown in U.S. Patent No. 4,903,707 to Knute entitled VENTRICULAR CATHETER ASSEMBLY is a different approach and has been found to be extremely useful in stabilizing a catheter used to sense pressure in the brain of a patient. An incision through the scalp to the skull is made and then a hole is bored through the skull. The bolt is then screwed into the bore hole and thereby establishes a sterile environment that reduces the chances for infection and firmly anchors the bolt in place in the skull. Through the bolt is a channel for receipt of an instrument such as a pressure sensing catheter. A threaded cap forces a clamp into contact with the catheter shaft as the cap is screwed onto the bolt body to hold the catheter in position in relation to the clamp, the bolt, and to the skull of the patient.

Requirements of such a bolt are that it be rapidly installable in the skull and that it work efficiently across a wide variety of skull types, including the much thinner pediatric skulls. The smaller pediatric skulls have much less thickness and in some cases do not provide the amount of material for the threads of the screw-type bolts to securely fasten to. It has been found that in such cases, some screw-type bolts do not work as well. Additionally, such a bolt must provide a fluid seal between it and the skull and a fluid seal between it and the inserted instrument or instruments as well as be easy to manipulate.

As used herein, an "instrument" includes a sensing catheter, drainage catheter, or other device designed for introduction into a biological location.

Additionally, a fluid seal for forming a sterile connection with the inserted instrument should be located as close to the patient's skull as possible to lessen the risk of infection.

Hence, those skilled in the art have recognized the need for a parenchymal bolt that not only secures an instrument in a desired position in relation to the ventricle of a patient, but that also reduces the risk of infection to the patient, is easy to install, permits rapid removal of the instrument, and that works efficiently for a wide variety of skulls. A device that is simple and inexpensive in construction, is easy to use, and is useable in a wide variety of conditions is also the subject of a recognized need. The present invention fulfills these needs and others.

SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention is directed to a low profile parenchymal bolt for fluid-tight installation into an opening in the skull. In one aspect, the bolt comprises an expandable body, a cap in contact with one end of the body, a base in contact with the other end of the body and an expansion activating device that interconnects the cap with the base wherein the expansion activating device causes the cap and base to move more closely together when the device is engaged thereby causing the expandable body to increase its outer diameter, and the expansion activating device allows the cap and base to move farther apart when disengaging thereby allowing the expandable body to decrease

its outer diameter, whereby when the expansion activating device is engaged, the outer diameter of the body makes contact with the skull opening.

In another aspect, the body comprises a control lumen and the expansion activating device interconnects the cap with the base through the control lumen of the body. In a further aspect, the control lumen is centrally located through the body.

In a more detailed aspect, the expansion activating device comprises a movable rod disposed between the cap and the base wherein the expansion activating device moves the rod thereby causing the base to move closer to the cap. In further detail, the base comprises an internally threaded shaft anchored to the base, the rod is threaded and engages the internal threads of the threaded shaft of the base, wherein the expansion activating device causes one of the rod and shaft to rotate thereby causing the rod and shaft and the cap and base to move closer together. In yet further detail, the rod comprises a screw rotatably mounted to the cap and engaging the threads of the internal threaded shaft, wherein the expansion activating device causes one of the screw and shaft to rotate thereby causing the screw and shaft and the cap and base to move closer together. In an even further detailed aspect, the threaded shaft is rigidly mounted to the base, the screw comprises a head located on an exterior of the cap with the screw disposed through the cap and engaging the threaded shaft of the base whereby rotating the screw draws the threaded shaft and the base toward the cap.

In yet another aspect, the screw and threaded shaft extend through the body along the central axis of the body. In a further aspect, the screw and threaded shaft are centrally located in the cap and the base and extend through the body along the central axis of the body.

In yet a further aspect in accordance with the invention, the bolt of further comprises a first instrument lumen having an inner diameter formed through the cap, the body, and the base and having a size for slidably accepting an instrument, wherein the first instrument lumen is located in an off-center position through the body, whereby moving the base and cap closer together causes the inner diameter

of the first instrument lumen to decrease in size thereby clamping an instrument located in the first instrument lumen in position.

In a further more detailed aspect, the bolt further comprises a second instrument lumen having an inner diameter and being formed through the cap, the body, and the base and having a size for slidably accepting an instrument, wherein the second instrument lumen is located in an off-center position through the body, whereby moving the base and cap closer together causes the inner diameter of the second instrument lumen to decrease in size thereby clamping an instrument located in the second instrument lumen in position.

In yet a more detailed aspect, the cap comprises a handle that may be grasped by the operator when the bolt is being manipulated. The handle is disposed laterally in relation to the cap, the handle having a size that may be grasped by an operator.

In another aspect, the cap is larger in diameter than each of the body and the base and in a further aspect, the cap is larger in diameter than the opening in the skull.

These and other aspects and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, illustrating by way of example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 presents an overall view of the use of a system for sensing pressure and temperature in the ventricle of a patient, and for draining fluid from that ventricle, using a low profile parenchymal bolt to mount a catheter in the skull of a patient in accordance with aspects of the invention;

FIG. 2 shows a drill for boring a hole in the skull of a patient for insertion of a parenchymal bolt shown and described in detail below and for insertion of the catheter shown in FIG. 1;

FIG. 3 is a perspective view of a low profile parenchymal bolt in accordance with certain aspects of the invention showing the bolt in a contracted configuration;

FIG. 4 is a perspective view of a low profile parenchymal bolt in accordance with certain aspects of the invention showing the bolt in an expanded configuration;

FIG. 5 presents an application of the bolt of FIG. 3 wherein two instruments have been mounted through the bolt and the bolt has been placed in position in the skull of a patient an is in the contracted configuration;

FIG. 6 presents the application of the bolt of FIG. 5 showing the bolt in the expanded configuration;

FIG. 7 presents a larger view of the cap of the bolt of FIG. 3;

FIG. 8 presents a larger view of the body of the bolt of FIG. 3; and

FIG. 9 presents a larger view of the base of the bolt of FIG. 3.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description, like reference numerals will be used to refer to like or corresponding elements in the different figures of the drawings. Referring now to FIG. 1 in more detail, there is shown a system 10 capable of monitoring a brain parameter of a living patient through an opening in the skull. Insertion of an instrument, in this case a catheter 12, into the brain 14 requires much surgical skill and has carried a significant risk of infection, especially when it has been necessary for the catheter to remain in position for an extended period of time. A catheter 12 shown in FIG. 1 can be quickly and easily inserted through the bolt 22 and forms a sterile connection with the skull 16 whereby the catheter can be left in place for a long period with the risk of infection greatly reduced.

In the case shown in FIG. 1, the catheter 12 comprises a ventricular catheter 12 designed generally for monitoring pressure in the brain and is inserted through an opening 18 in the skull 16 of a living person 20. A bolt 22 receives the catheter 12 and secures the catheter at a selected depth in the brain of the patient. The bolt 22 has a distal extremity adapted for sliding insertion into the opening 18 in the skull and is then expanded into contact with the opening, thereby securely mounting the bolt to the skull in a fluid tight relation. An elongated channel extends through the bolt 22 for receiving an instrument, such as the catheter 12, and as the bolt is expanded into contact with the opening 18, it also

clamps the instrument into a fixed position in the bolt and forms a fluid-tight seal with it.

The catheter 12 in this case includes a portion protected by an outer protective sheath 24 adapted to fit slidingly within the channel of the bolt and a flexible portion 26 adapted to penetrate into a ventricle 28 of the brain. The flexible portion 26 has an opening from the lumen of the catheter to an exterior surface of the catheter for communication between the lumen and any fluid adjacent the catheter. Located in the distal end of this catheter is a pressure sensor (not shown) similar to that of U.S. Patent No. 5,107,847 although different and/or additional sensors may be used.

Also shown in FIG. 1 are a coupling 30 and a monitor 32 connected to the coupling by a lead 34 containing optical fibers in this case. Also shown are a fluid collection vessel 36 and a drain tube 38 also connected to the coupling 30 that form a drain system 40 for draining fluid from the brain if necessary.

Referring now to FIG. 2, an optional installation kit comprises a drill 42 for drilling an opening 18 through the skull 16 to receive the bolt, a drill stop 44 adapted for installation on the drill, an Allen wrench 46, for installing the drill stop at a selected location on the drill to fix a maximum depth to which the drill can penetrate. Other means may be used to form the opening 18 in the skull 16.

Referring now to the perspective view of FIG. 3, an embodiment of a low profile parenchymal bolt 22 in accordance with aspects of the invention is shown. A cap 50 is preferably larger than the bored opening 18 in the skull 16 of a patient (FIG. 1). The cap 50 has a handle 52 for assisting in cap operations, as will be discussed in more detail below. With the laterally positioned handle 52, the cap may be the same size or smaller than the opening 18 of the skull as the handle will interfere with the cap being introduced into the opening. A body 54 of resilient material is engaged with the cap 50 and a base 56 is disposed on the opposite side of the body 54 from the cap 50. The base 56 has approximately the same diameter as the body 54, both of which have diameters smaller than the cap diameter, in this embodiment.

An expansion activating device is included with the bolt 22 that controls the movement of the base and cap towards each other. As the cap and base approach each other, the body is compressed and expands outwardly increasing its outer diameter in direct proportion to the amount of movement of the base and cap towards each other. In this embodiment, the base 56 includes a threaded shaft 58 protruding into a control lumen 60 formed in the body 54. A threaded screw 62, in this case a slot-head screw, is placed in an opening formed in the cap and also protrudes into the control lumen 60 in the body and into threaded engagement with the shaft 58 of the base 56. Rotating the screw in the appropriate direction, *i.e.* into the shaft, causes the base to move towards the cap, as described above.

The cap, body, and base also include and additional first lumen 64 for receipt of a first instrument 68 and a second lumen 66 for receipt of a second instrument 70.

Referring now to FIG. 4, the result of turning the screw 62 into the shaft 58 of the base is graphically shown. The base 56 moves toward the cap 50 as the screw is turned in a first direction. Such movement compresses the body 54 and due to its resilience, the body expands outwardly thus increasing its outer diameter. Because the screw 62, control lumen 60 and shaft 58 are centrally located in the body 54, the body expands symmetrically outwardly from them increasing its outer diameter and increasing the inner diameter of the control lumen 60. However, the expansion outward will reduce the size of the first and second lumina 64 and 66 putting pressure on and clamping in place any instruments located in those lumina.

The above effects are shown more clearly in the examples of FIGS. 5 and 6. Turning now to FIG. 5, an opening 18 has been formed in the skull 16 of a patient and the bolt 22 has been introduced such that the cap 50 is resting at the outer aperture of the opening. There is space between the body 54 of the bolt and the opening 18. Additionally, first and second instruments 68 and 70 have been placed in position through the bolt lumina 64 and 66 respectively. As can be seen, the diameters of the lumina are larger than the diameters of the instruments. The

instruments can therefore be moved through the lumina and placed in desired positions in the brain of the patient.

The screw 62 is now rotated into further engagement with the shaft 58 of the base to place the bolt in the configuration shown in FIG. 6. The base 56 moved closer to the cap 50 causing the outer diameter of the body 54 to increase and make a fluid-tight contact with the opening 18 of the skull thus securing the bolt 22 in a fixed position with the skull 16. Additionally, the lumina 64 and 66 of the body have decreased in size due to their locations off-center in the body 54. This reduction in size has caused them to clamp the first and second instruments 68 and 70 in fixed positions in relation to the bolt 22 and therefore the skull 16. These are also fluid-tight seals and are at the skull level. Turning the screw in the opposite direction, *i.e.*, out of the shaft, will cause the bolt to return to the configuration shown in FIG. 5.

Referring now to FIGS. 7, 8, and 9, the cap 50, the body 54, and the base 56 are shown individually. The cap comprises the laterally oriented handle 52 in the case of FIG. 7. The handle is integral with the cap and in a preferred embodiment, they are formed from a single piece of stainless steel with smooth transitions in all areas. No corners exist thereby lowering the possibility of contamination and infection to the patient. However, other designs are possible. For example, the handle may be made as a separate tube and press fit into an opening in the side of the cap for such a purpose. The cap also includes a screw opening 72, a first instrument opening 74, and a second instrument opening 76. The screw opening 72 is counter-sunk 73 in this embodiment so that the head of the screw does not protrude above the cap top surface. The orientation of the first and second instrument openings 74 and 76 in relation to the handle may be changed as desired as there is no required orientation of the body and base to the cap, other than aligning the openings and lumina of each with each other. The handle may be grasped by the operator to hold the bolt steady as the screw is turned. The cap may be formed of stainless steel or other biocompatible material.

While a laterally-extending handle 52 is shown in the drawings as a means for controlling the bolt 22, other handle approaches may be substituted.

The body 54 shown in FIG. 8 comprises in this embodiment the control lumen 60, and the first and second lumina 64 and 66 respectively, all of which extent completely through the body. The body is formed in one embodiment of silicone but may be made of other biocompatible material.

The base 56 is also formed stainless steel or other biocompatible material and includes the threaded shaft 58 integrally formed as one piece with the bottom disk 78. Alternatively, the threaded shaft may be a second part connected to the bottom disk 78 of the base such as by adhesive. The base also includes first and second lumina 80 and 82 respectively. As is apparent from a review of FIG. 6, the length of the threaded shaft 58 controls the amount of compression of the body 54 which in turn controls the amount of increase of the outer diameter of the body. The top of the shaft will contact the bottom surface of the cap thus limiting the increase in the outer diameter of the body. Making the shaft length shorter will result in a greater increase in the outer diameter of the body while making the shaft longer will result in a lesser increase in the diameter of the body.

For adult applications, the body 54 may be longer due to the increased thickness of the skull. The shaft 58 must than be longer. For pediatric applications, the body 54 may be shorter with a shorter shaft 58 due to the decreased thickness of the skull. However, in one pediatric application, an adult-sized bolt 22 was used with rings located on the body 54 distal to the cap 50. The bolt 22 was inserted into the opening 18 in the skull 16 with the rings on the outside of the skull at the cap. The rings had the effect of reducing the amount of penetration of the base 56 and body 54 of the bolt into the cranium. The expanded body 54 however still tightly held the bolt 22 in place with a fluid-tight seal in the skull. The rings were 2 mm thick in this application.

Thus, in accordance with the embodiments shown and described herein and referring again to FIG. 1, the physician can slide the catheter back and forth through the selected lumen of the bolt to position the flexible portion of the catheter in a desired location in the ventricle of the brain and then establish both a clamping of the catheter in position in the bolt and a fluid seal at the distal end of the bolt with the skull by simply rotating the screw in the appropriate direction.

In a typical use of the bolt 22, a physician makes an incision through the scalp and uses the drill and drill stop to drill an opening 18 through the skull 16 at a desired location. Then the bolt 22 is slid into the opening 18 until the cap 50 rests on the scalp. Next, a stylet (not shown) is inserted into the catheter 12 and the catheter is inserted through one of the lumina in the bolt 22 and positioned by the physician in the ventricle 28. The stylet is removed and next, the screw 62 is rotated into the shaft 58 of the base 56 causing the body 54 to expand outwardly into tight contact with the opening 18, fixing the bolt 22 in position in the opening 18 and fixing the catheter 12 in position in the bolt 22, constraining it against movement relative to the bolt, and sealing the bolt 22 to the catheter 12. Thus fluid tight seals against the leakage of cerebral spinal fluid are established. Finally, the monitor 32 and, if needed, the drain means 40 are connected to the catheter 12 through the coupling 30.

Because the bolt in accordance with the invention does not rely on threaded engagement with the skull but instead uses outward expansion and pressure to lodge the bolt in position, the bolt is well suited for use in pediatrics where the skull is thin and not well adapted to receive a threaded engagement. However, the bolt is suited for other skulls as well and provides for rapid, yet efficient, engagement with the skull. Because of the seals made with the skull and with an instrument mounted through the bolt, the risk of infection is lowered. Additionally, the lower profile of the bolt in accordance with the invention make it particularly suitable for bedside insertion with a drill kit. Additionally, the possibility of infection is reduced due to the smaller mass of the bolt 22, as well as the single piece, smooth construction of the cap of the bolt.

Additionally, the bolt provides a reduced likelihood of forming artifacts when imaging the patient due to its reduced use of ferric materials. The body 54 is formed of silicone in one embodiment, a non-ferric material, having the desired effect of reducing artifacts in MRI and CT scanning. Additionally, the amount of ferric material used may be further decreased by substituting other material for the cap and base.

As a further advantage, the bolt in accordance with the invention provides for easier and more secure installation. The need to form threads at the perpendicular to the skull is not necessary with the bolt disclosed here. Should the opening in the skull be at an angle, the bolt disclosed herein will nevertheless firmly grip, with a fluid tight seal, the opening and permit the use of instruments through the bolt. The possibility of the bolt pulling out of the non-perpendicular opening is reduced due to the use of outward pressure against the opening rather than a threaded engagement.

Although certain specific embodiments of the invention have been described and illustrated, the invention is not to be limited to the specific forms or arrangement of parts so described and illustrated, and various modifications and changes can be made without departing from the scope and spirit of the invention.

CLAIMS

What is claimed is:

1. A bolt for insertion into an opening in a skull, the bolt comprising:

an expandable body;

a cap in contact with one end of the body;

a base in contact with another end of the body; and

an expansion activating device that interconnects the cap with the base wherein the expansion activating device causes the cap and base to move more closely together when the device is engaged thereby causing the expandable body to increase its outer diameter, and the expansion activating device allows the cap and base to move farther apart when disengaging thereby allowing the expandable body to decrease its outer diameter;

whereby when the expansion activating device is engaged, the outer diameter of the body makes contact with the skull opening.

2. The bolt of claim 1 wherein:

the body comprises a control lumen; and

the expansion activating device interconnects the cap with the base through the control lumen of the body.

3. The bolt of claim 2 wherein the control lumen is centrally located through the body.

4. The bolt of claim 1 wherein the expansion activating device comprises:

a movable rod disposed between the cap and the base;

wherein the expansion activating device moves the rod thereby causing the base to move closer to the cap.

5. The bolt of claim 4 wherein:

the base comprises an internally threaded shaft anchored to the base;

the rod is threaded and engages the internal threads of the threaded shaft of the base;

wherein the expansion activating device causes one of the rod and shaft to rotate thereby causing the rod and shaft and the cap and base to move closer together.

6. The bolt of claim 5 wherein:

the rod comprises a screw rotatably mounted to the cap and engaging the threads of the internal threaded shaft;

wherein the expansion activating device causes one of the screw and shaft to rotate thereby causing the screw and shaft and the cap and base to move closer together.

7. The bolt of claim 6 wherein:

the threaded shaft is rigidly mounted to the base;

the screw comprises a head located on an exterior of the cap with the screw disposed through the cap and engaging the threaded shaft of the base;

whereby rotating the screw draws the threaded shaft and the base toward the cap.

8. The bolt of claim 7 wherein the screw and threaded shaft extend through the body along the central axis of the body.

9. The bolt of claim 7 wherein the screw and threaded shaft are centrally located in the cap and the base and extend through the body along the central axis of the body.

10. The bolt of claim 1 further comprising:

a first instrument lumen having an inner diameter formed through the cap, the body, and the base and having a size for slidably accepting an instrument;

wherein the first instrument lumen is located in an off-center position through the body;

whereby moving the base and cap closer together causes the inner diameter of the first instrument lumen to decrease in size thereby clamping an instrument located in the first instrument lumen in position.

11. The bolt of claim 10 further comprising:

a second instrument lumen having an inner diameter and being formed through the cap, the body, and the base and having a size for slidably accepting an instrument;

wherein the second instrument lumen is located in an off-center position through the body;

whereby moving the base and cap closer together causes the inner diameter of the second instrument lumen to decrease in size thereby clamping an instrument located in the second instrument lumen in position.

12. The bolt of claim 1 wherein the cap comprises a handle that may be grasped by the operator when the bolt is being manipulated.

13. The bolt of claim 12 wherein the handle is disposed laterally in relation to the cap and is formed from a single piece of material with the cap with smooth transitions.

14. The bolt of claim 1 wherein the cap is larger in diameter than each of the body and the base.

15. The bolt of claim 14 wherein the cap is larger in diameter than the opening in the skull.

16. A bolt for insertion into an opening in a skull and for clamping an instrument located through the bolt in position in the bolt, the bolt comprising:

an expandable body;

a cap in contact with one end of the body;

a base in contact with another end of the body; and

a first instrument lumen having an inner diameter formed through the cap, the body, and the base and having a size for slidably accepting an instrument;

wherein the first instrument lumen is located in an off-center position through the body;

an expansion activating device that interconnects the cap with the base wherein the expansion activating device causes the cap and base to move more closely together when the device is engaged thereby causing the expandable body to increase its outer diameter, and the expansion activating device allows the cap and base to move farther apart when disengaging thereby allowing the expandable body to decrease its outer diameter;

whereby when the expansion activating device is engaged, the outer diameter of the body makes contact with the skull opening and the inner diameter of the first instrument lumen decreases in size to clamp an instrument located in the first instrument lumen in position.

17. The bolt of claim 16 wherein:

the body comprises a control lumen; and

the expansion activating device interconnects the cap with the base through the control lumen of the body.

18. The bolt of claim 17 wherein the control lumen is centrally located through the body.

19. The bolt of claim 16 wherein the expansion activating device comprises:

a movable rod disposed between the cap and the base;

wherein the expansion activating device moves the rod thereby causing the base to move closer to the cap.

20. The bolt of claim 19 wherein:

the base comprises an internally threaded shaft anchored to the base;

the rod is threaded and engages the internal threads of the threaded shaft of the base;

wherein the expansion activating device causes one of the rod and shaft to rotate thereby causing the rod and shaft and the cap and base to move closer together.

21. The bolt of claim 20 wherein:

the rod comprises a screw rotatably mounted to the cap and engaging the threads of the internal threaded shaft;

wherein the expansion activating device causes one of the screw and shaft to rotate thereby causing the screw and shaft and the cap and base to move closer together.

22. The bolt of claim 21 wherein:

the threaded shaft is rigidly mounted to the base;

the screw comprises a head located on an exterior of the cap with the screw disposed through the cap and engaging the threaded shaft of the base;

whereby rotating the screw draws the threaded shaft and the base toward the cap.

23. The bolt of claim 22 wherein the screw and threaded shaft extend through the body along the central axis of the body.

24. The bolt of claim 22 wherein the screw and threaded shaft are centrally located in the cap and the base and extend through the body along the central axis of the body.

25. The bolt of claim 16 wherein the cap comprises a handle that may be grasped by the operator when the bolt is being manipulated.

26. The bolt of claim 25 wherein the handle is disposed laterally in relation to the cap and is formed from a single piece of material with the cap with smooth transitions.

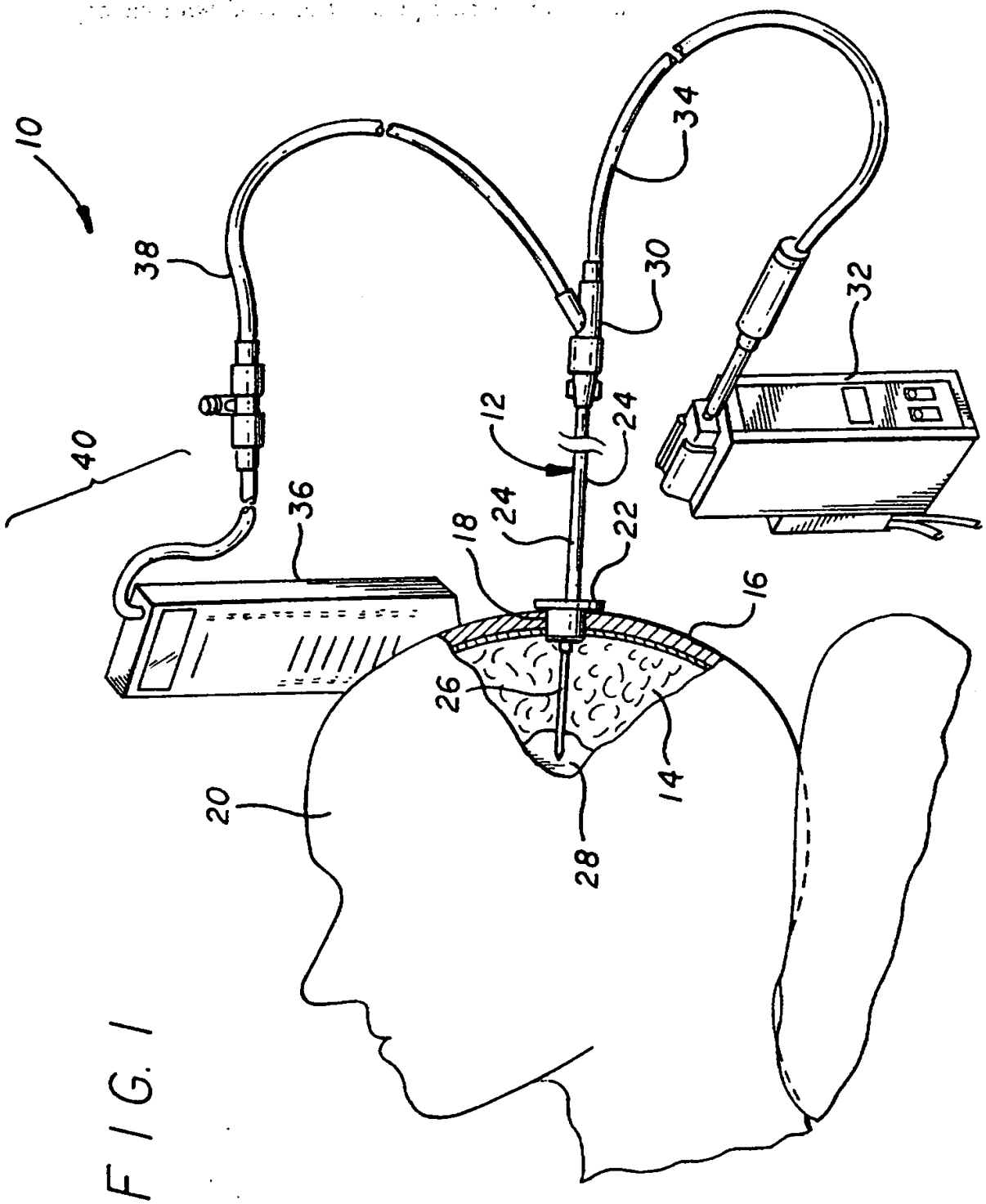


FIG. 1

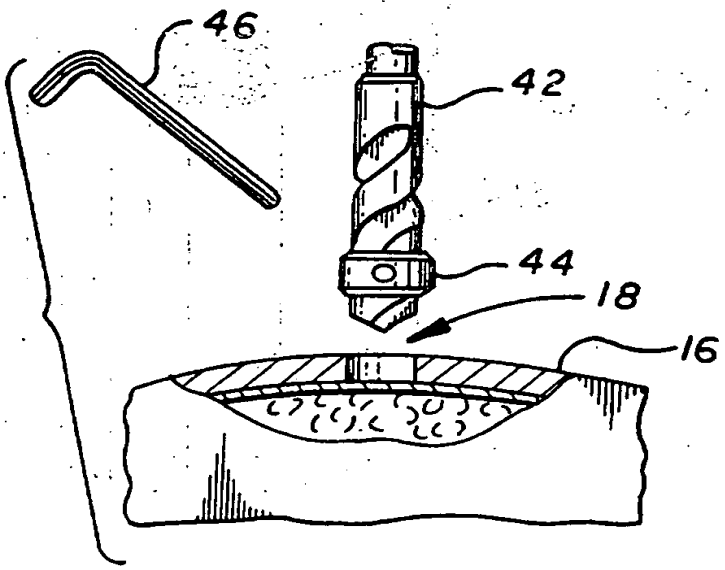


FIG. 2

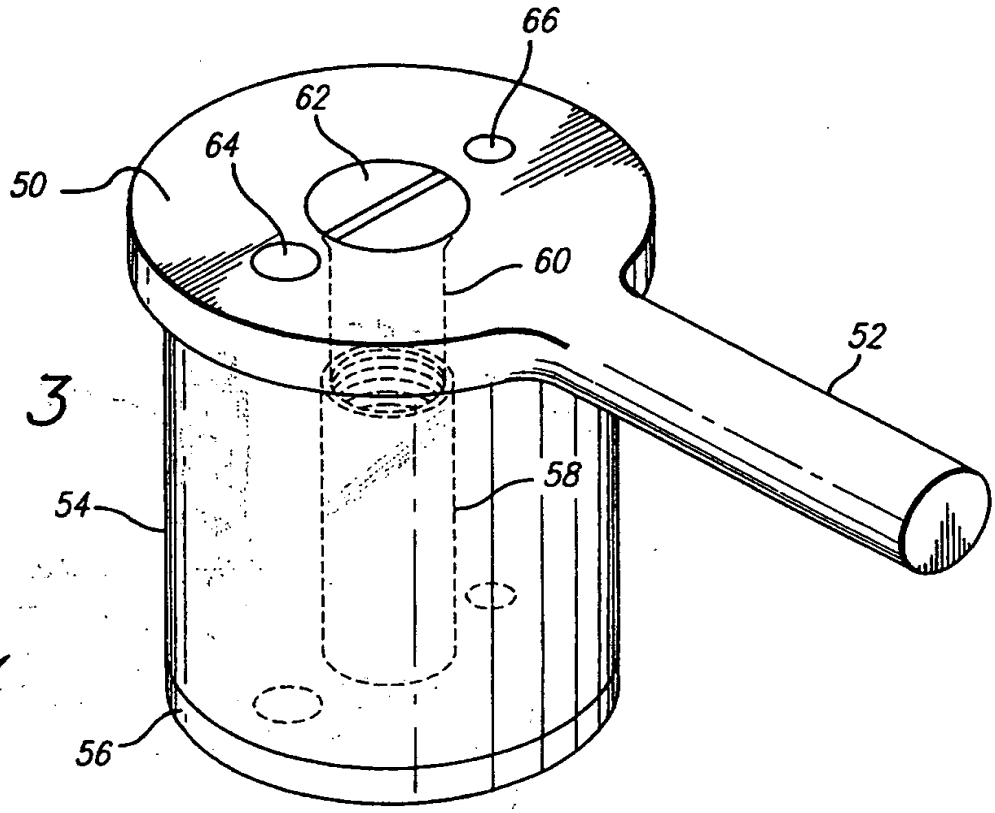


FIG. 3

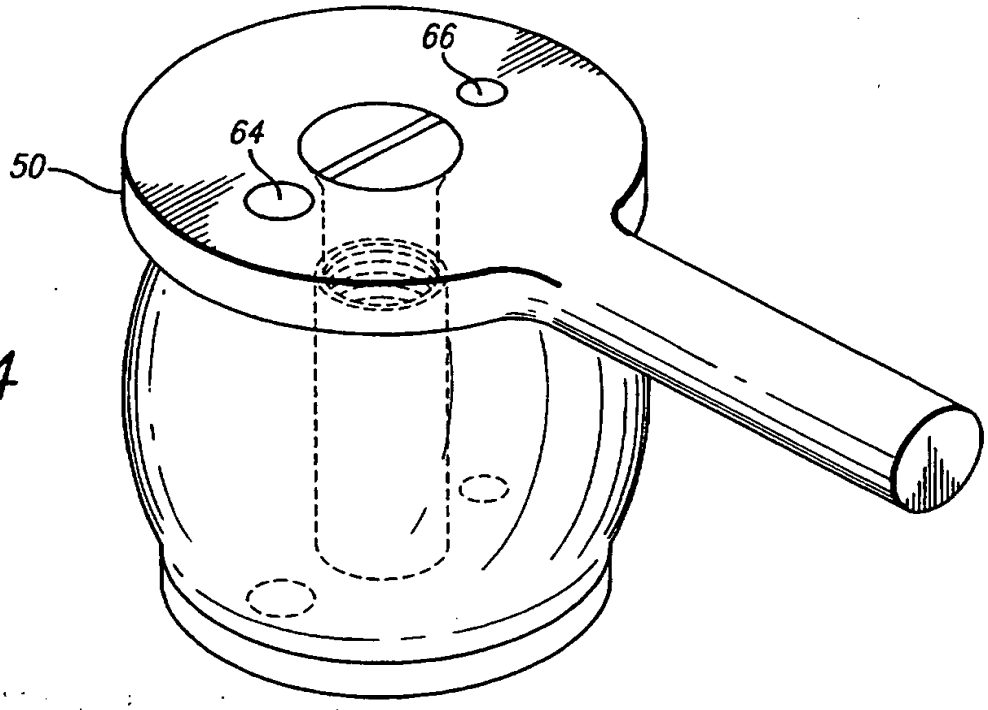


FIG. 4

FIG. 5

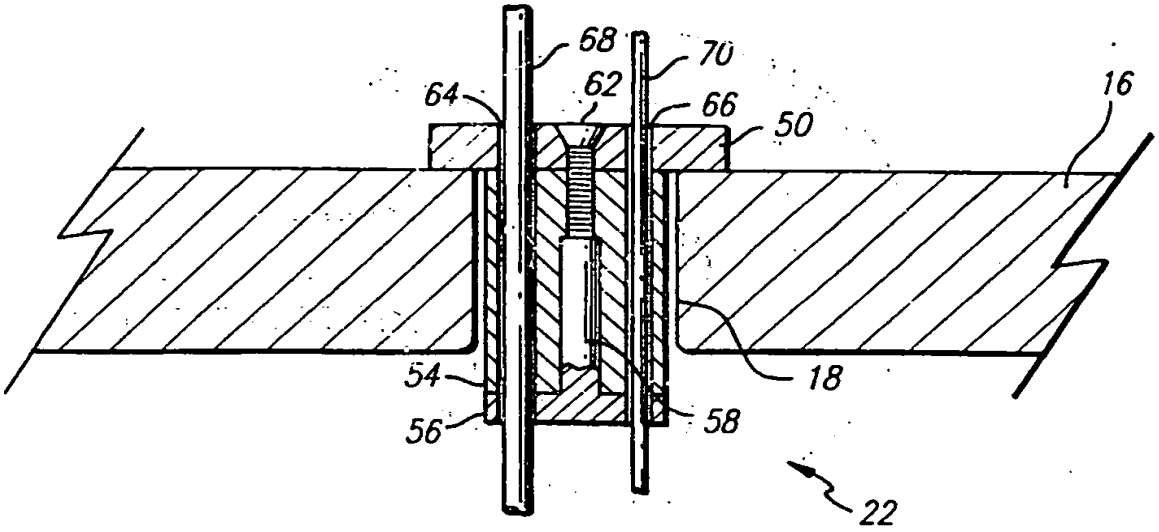


FIG. 6

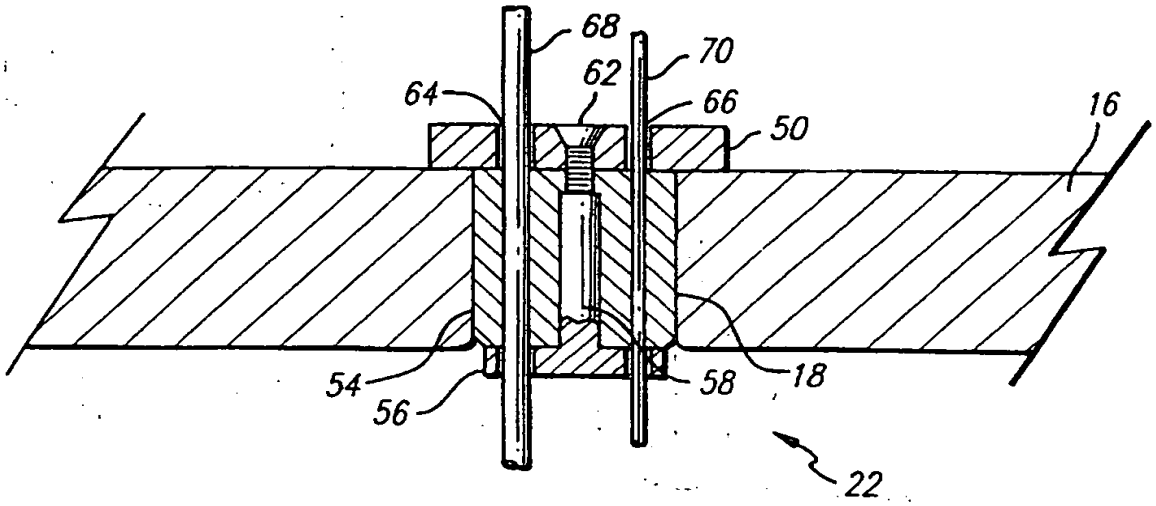


FIG. 7

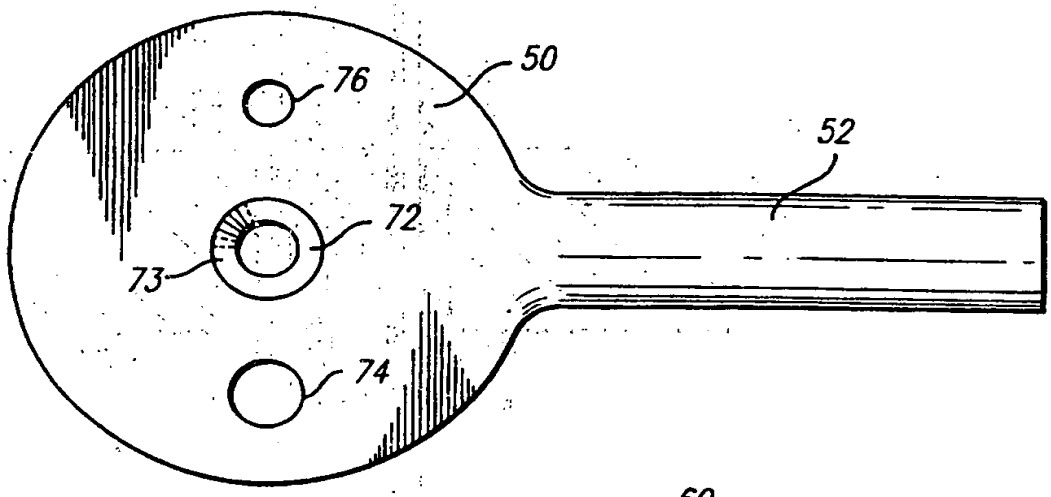


FIG. 8

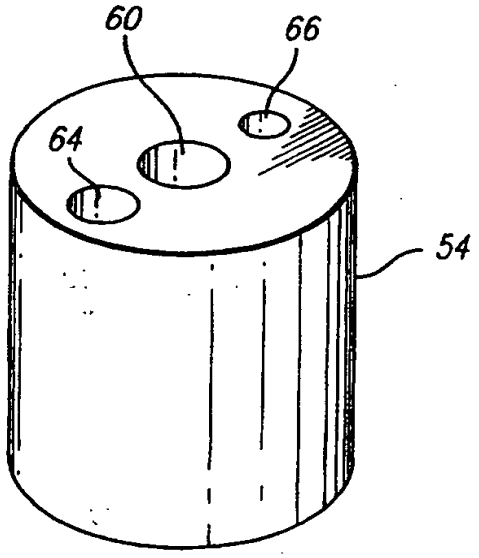
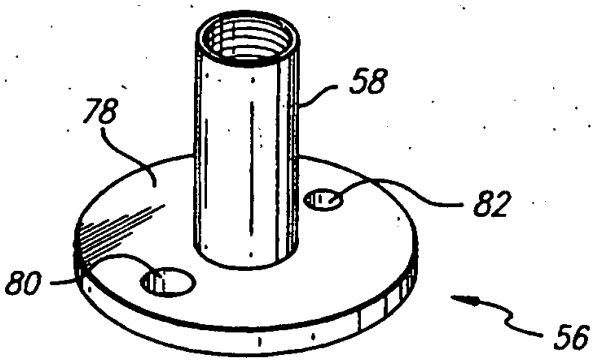


FIG. 9



INTERNATIONAL SEARCH REPORT

Internat. Application No
PCT/US 97/08130

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/03 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 83 03190 A (SWEENEY PAUL L JR) 29 September 1983 see the whole document	1-4 5-10, 14-21
A	US 5 054 497 A (KAPP JOHN P ET AL) 8 October 1991	1-10, 14-21
A	US 4 903 707 A (KNUTE WALLACE L ET AL) 27 February 1990 cited in the application see the whole document	1,16

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
31 July 1997	24.09.97

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna l Application No
PCT/US 97/08130

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